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Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: "180-Day Generic Drug Exclusivity For Abbreviated New Drug Applications," Docket No. 85N-0214, 64 Fed. Reg. 42873, August 6, 1999.

Sir/Madam:

On behalf of the Generic Pharmaceutical Industry Association (GPIA), I am submitting comments and objections on "180-day Generic Drug Exclusivity for Abbreviated New Drug Applications," Docket No. 85N-0214, FR 42873, August 6, 1999.

GPIA is comprised of the manufactures and distributors of generic medicines as well as the providers of technical services and goods to these firms. Many of our members will be directly impacted by implementation of the subject proposed rule, amending the agency's current regulations on supplements and other changes to an approved application.

GPIA has long taken a leading role in advocating for laws and regulations that assure the most expeditious availability of high-quality, low-cost generic drugs to American consumers. As the U.S. population ages during the early years of the next century, GPIA's mission will take on added importance, and we stand ready and eager to work together with the FDA and Congress to assure that all Americans have the most affordable access possible to life saving, and life-improving, pharmaceutical products. Thus, we are pleased to offer the following comments on the proposed regulations.

SUMMARY

While GPIA recognizes the hard work and extraordinary intellectual effort taken by the agency in developing these proposals, GPIA is concerned that several elements of the proposal place more emphasis on defeating exclusivity in particular situations, than on preserving the important incentives Congress intended by enacting the exclusivity provision. For that reason, and other specific reasons mentioned herein, GPIA: Opposes the proposed triggering period, shared exclusivity, and limitations on transferability of exclusivity. Moreover, GPIA urges the agency to withdraw its opposition to "rolling exclusivity," and the recent court cases that permit a "case or controversy" dismissal of a declaratory judgment action to serve as a court decision trigger. Finally, GPIA offers several recommendations to clarify the regulations and improve the functioning of the exclusivity scheme. These recommendations include adoption of a single 30-month stay period per listed drug product, and specifying that the court decision trigger is activated only by a court decision involving the last unadjudicated patent. These, and other issues are discussed in more detail below.

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THE PROPOSED "TRIGGERING PERIOD"

GPIA applauds the Agency's recognition that accelerating market entry of generic drugs must be a high priority in developing a regulatory response to the judicial invalidation of the "successful defense" requirement in Mova Pharmaceuticals Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998). Thus, GPIA has studied with great interest the Agency's proposal to establish a "triggering period" mechanism.

As GPIA understands the proposal, the triggering period would be a 180-day period that would begin if a subsequent Paragraph IV ANDA receives tentative approval before a statutory triggering event – either commercial marketing by the first applicant, or an applicable "court decision" involving any applicant – has occurred to start the first Paragraph IV ANDA applicant's exclusivity period. If no triggering event occurs during the triggering period, subsequent ANDAs could be approved immediately upon expiration of the triggering period, and the first applicant would lose exclusivity.

The start of the triggering period would be deferred, and the first applicant's eligibility for exclusivity conditionally preserved, in two situations:

- if the first applicant is sued and the litigation is ongoing, the triggering period would not start until the expiration of the 30-month statutory stay applicable to the first ANDA.[1] *Proposed* 21 C.F.R. § 314.107(c)(5)(i)(C);

- if during litigation involving the first applicant, the district court grants a preliminary injunction pursuant to 21 U.S.C. § 355(j)(5)(B)(iii)(III) prohibiting commercial manufacturing or marketing of the applicant's drug until the court decides the issue(s) of patent validity, enforceability, and/or infringement, the triggering period would start on the date the preliminary injunction expires. *Proposed* 21 C.F.R. § 314.107(c)(5)(i)(D).

In addition, the triggering period would not begin until the expiration of any other exclusivity for the reference drug, such as pediatric exclusivity or new chemical entity exclusivity. Significantly, the proposal does not defer the triggering period for a first applicant who is sued, and whose 30-month stay period has expired before a court decision is issued. See Proposed 21 C.F.R. § 314.107(c)(5)(i)(E). This provision would thus force a first applicant to either go to market prematurely, at risk of treble damages if it is found to infringe the patent, or to lose the exclusivity altogether if it refuses to take such a risk and the infringement case is not concluded within 30 months plus the 180-day triggering period.

[1] Proposed 21 C.F.R. § 314.107(c)(5)(i)(C) specifies only that the triggering period will be deferred pending "the expiration of the 30 months described in paragraph (b)(3)(i)(A)." Paragraph (b)(3)(i)(A) describes the possibility of judicial extension (or shortening) of the 30-month period, and GPIA assumes that FDA intended that the start of any triggering period would also be stayed during any judicial extension of the 30-month period.

After careful review and analysis, GPIA recommends that FDA not adopt the triggering period concept, because it adds additional requirements and conditions that are not contemplated by, and are in conflict with, the controlling statutory provisions of 21 U.S.C. § 355(j)(5)(B). Thus, it is likely to be struck down upon judicial challenge, further delaying the implementation of a fair and workable framework to deal with these critically important issues. Moreover, even if the triggering period would survive judicial scrutiny, it would be insufficient to fully accomplish the purpose of ending inappropriate delays in generic market entry.

The proposed triggering period concept fundamentally conflicts with the statutory provisions because the statute clearly provides only two ways in which the 180-day exclusivity period may be started, or "triggered": (1) the first applicant begins commercial marketing of the drug, and (2) a "court decision" is issued holding the patent invalid, unenforceable,[2] or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv). The statute does not allow the 180-day exclusivity period to be disregarded simply by virtue of FDA tentatively approving a subsequent applicant's ANDA, even if the first applicant is "allowed" 180 days to trigger the exclusivity period after such subsequent approval. Thus FDA's proposal would essentially amend the statute by adding an exception to the statutory exclusivity provision, under which the first applicant's exclusivity period would be deemed to have been triggered, and to have expired, without either type of triggering event having occurred.

The agency states in the proposed rule that the courts in Mova and Purepac suggested that the triggering period would be a permissible approach to avoiding undue delays in the marketing of generic drugs. This assertion fundamentally misconstrues the opinions in those cases. It is especially noteworthy that one of the primary bases for the Mova court's invalidation of the successful defense regulation was that "its practical effect is to write the commercial-marketing trigger out of the statute." Mova, 140 F.3d at 1070. The anomalous aspect of the current proposal is that proposed section 314.107(c)(5)(i)(E) would eliminate exclusivity for a first applicant who is still involved in defending patent infringement litigation after the 30-month stay period has expired, if the applicant does not rush to market before a court decision issues. Such an applicant is in the same position as Mova Pharmaceuticals was in with respect to micronized glyburide – i.e. Mova was a first Paragraph IV applicant still mired in patent litigation when the FDA approved the ANDA of a subsequent applicant (Mylan) before Mova's patent litigation had ended. Here, the agency has merely added a 180-day buffer period to the "successful defense" requirement that was struck down by the courts in Mova. The courts did not strike down the successful defense requirement because it eliminated exclusivity too quickly, but rather because it eliminated exclusivity at all. If regulating one trigger out of the Act was unlawful in Mova, it seems likely that regulating both triggers out of the Act would also be unlawful.

In addition, the triggering period proposal is internally inconsistent and conflicts with existing regulatory interpretations that the agency has not proposed to change. For example, where a preliminary injunction has been entered prohibiting the commercial marketing of the first applicant's drug, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii)(III), the triggering period would, under the terms of the proposal, begin on the date the district court issued a final decision of patent invalidity, non-infringement, or unenforceability, because under federal court procedures, a final decision on the merits in favor of the generic applicant generally operates to dissolve any preliminary injunction against the generic applicant. Thus, the start of the 180-day triggering period would be based on the district court's decision, notwithstanding any appeal, whereas for all other purposes, including

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[2] The unenforceability of a patent as a basis for Paragraph IV Certifications and triggering court decisions is mandated by the Federal Circuit decision in Merck & Co., Inc. v .Danbury Pharmacal, Inc., 694 F.Supp. 1 (D. Del. 1988); aff'd, 873 F.2d 1418 (Fed. Cir. 1989); See also Teva Pharmaceuticals USA, Inc. v. FDA, 182 F.3d 1003, 1009 (D.C. Cir. 1999).

final approval of the first applicant's ANDA, the agency requires a "final court decision," meaning the decision of an appeals court, or the lapsing of the patent holder's right to appeal. 21 C.F.R. § 314.107(b)(3)(ii), and (e). As a result, a victorious Paragraph IV challenger will not be allowed to receive final approval until any appeal is resolved in its favor, which will invariably take much longer than 180 days, by which time its exclusivity period will have been nullified by expiration of the triggering period. The result is that winning a Paragraph IV litigation at the district court level will assure that the first applicant will be deprived of its exclusivity period, and indeed, will not be able to market until well after any subsequent applicants who are not sued. This is surely a perverse and unintended result.

In addition to the foregoing inconsistencies inherent in the triggering period approach, the triggering period provisions, as currently written, could introduce new, potentially crippling ambiguities into the 180-day exclusivity scheme. For example, the triggering period will only apply in situations where "a subsequent applicant receives a tentative approval letter for its drug product stating that the first applicant's eligibility for 180-day exclusivity is the only obstacle to final approval of the subsequent ANDA. . . ." *Proposed* § 314.107(c)(5)(i) (emphasis added). However, because FDA nowhere defines the term "obstacle," GPIA is concerned that a subsequent applicant might challenge the meaning of this term in an effort to force the start of a triggering period and defeat the first applicant's exclusivity period. Moreover, FDA's usual practice in issuing tentative approval letters is to specifically state that final approval remains contingent upon the applicant submitting a "60-90 day amendment" updating the ANDA with any changes in labeling, chemistry, manufacturing, or controls for the drug product. A patent holder might argue that this requirement is an additional "obstacle" to the subsequent applicant's final approval so as to defeat operation of the triggering period, thus further delaying the start of generic competition. If FDA does adopt a triggering period approach, GPIA urges the agency to clarify these provisions to eliminate any uncertainties and potential loopholes to its intended operation.

While the statutory authority for imposing a triggering period is questionable, FDA does have adequate authority to exercise regulatory power over Orange Book patent listings which will accomplish the intended goals of the trigger period to reduce or eliminate delays in generic drug availability. To most effectively achieve the clear statutory goals and eliminate the types of marketing delays that have beset the industry and harmed consumers in recent years, the FDA must reform its administration of the Orange Book. The agency has been too passive in allowing the listing of any patent submitted, and sitting on the sidelines whenever a generic company identifies an improperly listed patent. FDA has the statutory authority to more closely monitor the types of patents listed in the Orange Book, and it is no excuse for the agency to disclaim any knowledge or ability to evaluate patents for qualification for Orange Book listing. Indeed, Hatch-Waxman's formal title, "The Drug Price Competition and Patent Term Restoration Act," suggests that Congress expected FDA to exercise its best efforts in evaluating those patent issues relevant to the agency's administration of the Act. FDA's failure to do so with respect to the Orange Book is an abdication of its statutory responsibility.

SHARED "FIRST FILER STATUS"

The 180-day exclusivity period is a powerful and important incentive to achieve the earliest possible generic market entry for the benefit of American consumers. Given the price behavior in markets with multiple generic competitors, any "sharing" of exclusivity would be akin to no exclusivity at all. The proposed rule would define "first applicant" for purposes of establishing eligibility for the 180-Day exclusivity period to include "all applicants filing substantially complete ANDAs with Paragraph IV Certifications for the same drug product on the first day that the agency receives applications with a Paragraph IV Certification for the drug product." *Proposed* 21 C.F.R. § 314.107(a)(2). The effect of this proposal would be to allow an unlimited number of applicants to share "exclusivity" for a drug product, thus diluting, or effectively destroying, the incentive to challenge drug patents. GPIA opposes this proposal.

In order to effectively maintain the important incentive to challenge patents, the 180-Day Delay Period must remain a true single entity "exclusivity." The clerical difficulties cited by FDA as justification for this proposal are unconvincing. At least in situations where multiple Paragraph IV ANDAs may be expected to be filed on the same day – i.e. the date after the expiration of the fourth anniversary of the NDA approval, or an applicable pediatric exclusivity period – FDA could easily designate a special "in-box" or contact person to receive Paragraph IV ANDAs and time-stamp the applications in the order they are received. This would make it advantageous to submit ANDAs in person rather than by mail, but that minor burden on the industry is well worth the potential reward of a true exclusivity period. Moreover, FDA could ease its own burden in these situations by, for instance, accepting confidential advance notifications from applicants of the intention to file a Paragraph IV ANDA on the relevant day after expiration of an NCE or pediatric exclusivity for a particular drug, so that the agency can make appropriate arrangements to determine the true order of submission.

Establishing the precise order of same-day filings would not impose a significant burden on the agency. As of November 4, 1999, there are only 110 drugs listed in the Orange Book that have more than one remaining year of unexpired NCE exclusivity (and thus are not yet eligible to be the subject of a Paragraph IV ANDA), and that also are covered by one or more unexpired listed patents.[3] These are the drugs for which multiple Paragraph IV ANDAs are most likely to be filed on the same day (i.e. the end of the fourth year of NCE exclusivity). Thus, FDA will potentially face multiple first-day Paragraph IV filers no more than 110 times during the next four years. It would be arbitrary and capricious for FDA to deny the generic industry the potential for a true exclusivity period for these drugs, when granting such exclusivities would require that the agency take a small extra clerical step less than three times per month, on average.

Finally, in the event more than one applicant is present at the designated FDA location at midnight the first day applications will be accepted for a drug, and each such applicant's ANDA is ultimately accepted for filing, a tiebreaker system should be adopted in order to award first filer status, even if the tiebreaker is a random drawing.

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[3] Approved Drug Products With Therapeutic Equivalence Evaluations (19th ed. 1999), Patent and Exclusivity List, available at http://www.fda.gov/cder/orange/19bookpub.pdf, and http://www.fda.gov/cder/orange/docket.pdf. (accessed Nov. 1, 1999).

ROLLING EXCLUSIVITY MUST BE PROSPECTIVELY ALLOWED

The agency proposes to limit eligibility for exclusivity to only "first" Paragraph IV applicants, even if the "first" applicant abandons its Paragraph IV patent challenge as a result of losing a patent infringement lawsuit brought by the patent holder, or for any other reason, including a settlement with the patent holder. See *Proposed* § 314.107(e)(2), and (3). GPIA opposes this limitation on eligibility for the exclusivity period, and urges the agency to adopt a "rolling exclusivity" scheme so that the next-filed Paragraph IV applicant becomes eligible for a potential 180-Day Delay Period if, before any triggering event has occurred, either (1) a "first applicant" amends its Paragraph IV Certification to a Paragraph III Certification; (2) the first applicant withdraws its ANDA entirely; or (3) the first applicant is determined to have filed a sham, or fraudulent application. This approach more directly implements the statutory language and purposes by rewarding the first ANDA applicant who does not abandon its effort to open the market to full generic competition by maintaining a Paragraph IV challenge to the patent.

Rolling exclusivity is also consistent with the statutory language establishing eligibility for the 180-day exclusivity period. The statutory 180-Day Delay Period provision states:

> (iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after –
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> > (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
> >
> > (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,
> >
> > whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv)

The effect of this statutory provision is that a 180-day delayed effective approval date must be imposed upon all Paragraph IV applicants for which there is a previously filed ANDA continuing a Paragraph IV patent challenge. Although there are some who have argued that the word "continuing" is a typographical error, and that "containing" is the word Congress intended,[4] the end result must be the same in either case. This is because the statute bases the application of the 180-day period upon the status of an ANDA as a subsequent Paragraph IV application – i.e. an ANDA that fits the criteria set forth in 21 U.S.C. § 355(j)(5)(B)(iv). A "first" applicant's abandonment of its Paragraph IV Certification does not change the fact that a third Paragraph IV applicant still fits the definition of "an applicant for which a previous application [i.e. the second ANDA] has been submitted" continuing/containing a Paragraph IV Certification. Thus, the plain language of the statue (using either

[4] Indeed one pending lawsuit, Pharmachemie B.V. v. Henney, No. 99-801 (D.D.C. filed Mar 30, 1999), tangentially raises this terminological issue, although in a different context.

"continuing" or "containing") operates to delay the effective date of the third (and later) Paragraph IV ANDAs, resulting in a potential exclusivity period for the original second applicant. To implement the statute as FDA proposes here, without rolling exclusivity, would be contrary to the statute's plain language. Because a "rolling exclusivity" interpretation would be a significant change from current policy, however, it should be implemented on a prospective basis only following the effective date of the final rule.

FDA SHOULD NOT ESTABLISH A NEW CONTENT-BASED STANDARD FOR DETERMINING WHETHER A FIRST PARAGRAPH IV ANDA QUALIFIES FOR EXCLUSIVITY

GPIA is concerned that FDA appears to be proposing a substantive modification of the criteria for exclusivity eligibility, specifically, the definition of "substantially complete" in proposed section 314.107(a)(2). That definition states that an ANDA will only be considered substantially complete – and thus eligible for exclusivity – if it contains "a complete statistical analysis of required bioequivalence studies demonstrating that the drug product proposed in the ANDA meets the appropriate bioequivalence standard." 64 Fed. Reg. at 42,885 (emphasis added). The result of this change would be to allow FDA to deny exclusivity to a first applicant long after its ANDA has been accepted for filing, based upon factors the applicant may have had no reason to be aware of at the time it developed its studies and submitted its application. Thus, under FDA's proposal, an applicant could be denied exclusivity based upon reasonable differences of opinion between the applicant and the agency as to the appropriate bioequivalence standards for a particular drug, or as to the adequacy of particular studies. By putting exclusivity at risk in such circumstances, first applicants would be less likely to cooperate with the agency when questions arise regarding submitted biostudies, and any differences of opinion are more likely to be litigated, rather than resolved cooperatively through scientific dialogue, or when appropriate, the completion of additional confirmatory studies. GPIA urges the agency to deem an ANDA to be substantially complete as of the date it was submitted, so long as it is ultimately accepted for filing.

NO LAWSUIT MAY BE REQUIRED FOR EXCLUSIVITY ELIGIBILITY

GPIA supports FDA's decision to follow the court's ruling in Purepac v. Friedman, 162 F.3d 1201 (D.C.Cir. 1998), that the "first applicant" need not be sued for patent infringement in order to be eligible for the 180-Day Delay Period.

THERE SHOULD BE ONLY ONE 30-MONTH STAY PERIOD FOR EACH DRUG PRODUCT

In the event FDA refuses to recognize the exclusivity eligibility of subsequent Paragraph IV applicants (i.e., no "rolling exclusivity"), it follows that subsequent ANDAs should not be held to separate 30-month stays, and the exclusivity period of the first filer should be the only impediment to market entry for subsequent Paragraph IV filers, absent an affirmative court order barring such entry. Thus, GPIA urges FDA to adopt a regulation that would result in only a single 30-month stay period being imposed upon all Paragraph IV applicants who are sued for patent infringement as a result of a Paragraph IV challenge to a particular drug, if

the agency refuses to recognize rolling exclusivity. Under this approach, if the first applicant is sued within 45 days of its Paragraph IV Certification, and subsequent applicants are also sued, the subsequent applicants will only be subject to whatever time remains on the first applicant's 30-month stay. This approach would supersede the current regulatory interpretation whereby each Paragraph IV ANDA applicant who is sued is subject to its own 30-month period starting on the date the lawsuit is filed. This proposal is consistent with the structure and intent of 21 U.S.C. § 355(j)(5)(B), and more suitably serves the underlying purpose of expediting generic market entry.

The purpose of the 30-month stay is to protect patent holders from potentially infringing generic sales before the courts have had the opportunity to rule on the patent validity, enforceability, and/or infringement issues raised in a Paragraph IV patent infringement action against the generic filers. However, in cases brought against subsequent Paragraph IV applicants, the 30-month stay is unnecessary because the subsequent applicant will be unable to obtain final approval until expiration of the first applicant's 180-day exclusivity period. Where the first applicant was also sued, the 30-month stay should usually be sufficient to allow the courts to reach a decision on the merits, and where the ruling is in favor of the first applicant, that will trigger the exclusivity period and the patent holder will not be entitled to protection against generic competition. Thus, the imposition of separate 30-month stays upon subsequent applicants serves only as an additional and unnecessary barrier to generic competition. In situations where the first applicant loses the Paragraph IV patent infringement case – and thus, assuming no rolling exclusivity, no applicant is eligible for exclusivity – and a subsequent applicant is also involved in its own litigation, the court retains jurisdiction to enter a preliminary injunction prohibiting marketing by the subsequent applicant until the litigation is concluded. Thus the patent holder is fully protected in this situation as well without the unnecessary burden of imposing a separate 30-month stay on the subsequent applicants. Alternatively, if FDA does not adopt the single 30-month stay period as a general rule, under no circumstance should there be a new 30-month period for lawsuits arising out of Paragraph IV Certifications to patents listed after patent litigation has ensued pursuant to a pervious listed patent, as this will only serve to encourage more of the anti-competitive Orange Book abuses that have been seen in recent years, and is not necessary to protect any legitimate interests of patent holders.

TRANSFER OF EXCLUSIVITY

The agency has proposed to place limitations on the utility and value of the 180-Day Delay Period by prohibiting any transfer of exclusivity to a particular subsequent applicant until the exclusivity period has been started by a triggering event. GPIA opposes this limitation and urges FDA to allow transfers at any time a first applicant is eligible for the exclusivity period, even if the period has not yet begun. The agency's proposal would devalue any transferred exclusivity because it is, as a practical matter, impossible for a subsequent applicant to receive the transfer, obtain final approval, and begin its own marketing all on the first day the exclusivity period commences, or indeed, any time close to that date. Thus, any transferred exclusivity would necessarily be for a period of less than 180 days, with a correspondingly lower value to the applicant.

FDA offers no reason why a first applicant may not effectively transfer any exclusivity it may earn prior to the triggering date of that exclusivity, other than the fact that the applicant may never finally perfect the right to exclusivity. Of course if that situation transpires, the subsequent applicant would also not be entitled to exclusivity. This should be a matter of negotiation between a first applicant and any potential beneficiary of the transfer and not a matter that FDA should prohibit out of hand.

THE COURT DECISION TRIGGER SHOULD ONLY OCCUR UPON A DECISION INVOLVING THE LAST REMAINING PATENT BLOCKING THE FIRST FILER FROM GOING TO MARKET

Where there are multiple listed patents for a particular drug and a first Paragraph IV applicant is sued by the patent holder, the 180-day exclusivity period should not begin until there has been a court decision of invalidity, non-infringement or unenforceability with respect to the last patent blocking the first filer's ANDA. In other words, where multiple patents are at issue in the first filer's ANDA, and a court decides that one of the patents is invalid, unenforceable or not infringed, but there are additional patents upon which the court has not yet ruled, the first applicant's 180-day exclusivity period should not be triggered merely because the dispute over one of several blocking patents has been resolved. This approach is necessary to maintain the viability of the 180-day exclusivity period as an incentive to challenge drug patents, because otherwise a partial court decision on a minor or tangential patent could result in the loss of exclusivity long before the courts have ruled regarding the more significant patents blocking generic competition. It is also consistent with current 21 C.F.R. § 314.107(b)(4), which allows approval of an ANDA with multiple patent certifications only "on the last applicable date." This could be accomplished by re-phrasing the term "relevant patent" in section 314.107(c)(1)(ii) to the plural "relevant patents." It might also be accomplished by separately defining "relevant patent" to mean the last listed patent that blocks market entry by the first applicant.

THE DISMISSAL OF A HATCH-WAXMAN DECLARATORY JUDGMENT ACTION MUST SERVE AS A COURT DECISION TRIGGER

GPIA agrees with the agency's decision to recognize that the statute unequivocally requires the start of the first applicant's 180-day exclusivity period upon a court decision in a declaratory judgment action brought by a subsequent applicant against the patent owner. However, GPIA disagrees with the agency's refusal to recognize that a "case or controversy" dismissal of such a lawsuit, based upon a finding that the generic applicant has no reasonable apprehension of being sued for infringement if it were to begin marketing its version of the drug, does not constitute a "court decision" for purposes of triggering the exclusivity period under 21 U.S.C. § 355(j)(5)(B)(iv). This issue has recently been considered in Teva Pharmaceuticals USA, Inc. v. FDA, 182 F.3d 1003 (D.C. Cir. July 20, 1999), followed on remand, No. 99-67 (D.D.C. Aug. 19, 1999), in which the D.C. Circuit and the U.S. District Court have both ruled that the case or controversy dismissal of Teva's Hatch-Waxman declaratory judgment action respecting Roche's listed patent for ticlopidine did constitute a "court decision" for purposes of triggering the start of TorPharm's (the first Paragraph IV applicant) 180-day exclusivity period.

This outcome is also consistent with the D.C. Circuit's opinion in Mova v. Shalala, 140 F.3d at 1073-74, n.18, in which the court stated that it would be permissible for FDA to treat such dismissals as court decision triggers. Although TorPharm and the agency have now appealed the district court's final judgment to the D.C. Circuit (Teva's initial appeal involved the denial of a preliminary injunction), there is no basis to expect that the Court will, upon its third consideration of this issue, depart from this established interpretation. Moreover, as Teva demonstrated in the Court of Appeals, without treating case or controversy dismissals as triggering court decisions, the statutory declaratory judgment action trigger mechanism would be rendered practically useless

because patent holders would routinely disclaim any intention of suing subsequent applicants while taking all possible steps to delay market entry by the first applicant. Teva, 182 F.3d at 1009 (FDA's position "means that the patent holder could manipulate the system in order to block or delay generic competition by stating that the patent holder will not enforce its patent against Paragraph IV challenger."). Accord, Mova, 140 F.3d at 1073-74, n. 18.

And, contrary to FDA's assertion in the preamble to this proposed rule, even if the "triggering period" approach is adopted, it would not render the declaratory judgment dismissal rule unnecessary. To the contrary, it would continue to foster unnecessary delays by refusing to allow meritorious subsequent applicants to start the exclusivity clock of recalcitrant or unmeritorious first patent challengers. Finally, even if FDA does not recognize case or controversy dismissals as triggering court decisions, the courts, under Teva, will. As a result, FDA will be involved in a lawsuit every time it refuses to follow the Teva decision. Surely that result does not represent an efficient use of the agency's scarce resources, and accordingly FDA should amend the proposed rule to explicitly recognize that case or controversy dismissals must be treated as court decision triggers under the Act.

EFFECTIVE DATE OF CHANGES

FDA should be aware that any changes adopted pursuant to the pending proposal will cause additional short term confusion and may frustrate the expectations of some companies based upon the current regulatory approach. Thus, FDA should apply any new regulatory approach adopted under this proposal on a prospective basis, and only for drug products for which no paragraph IV certification has been filed prior to the effective date of the final regulations. This will allow already-filed paragraph IV ANDAs to remain subject to the current regulatory approach so that paragraph IV ANDAs filed after the effective date cannot use the new regulations to alter the exclusivity expectations of first paragraph IV applicants.

Respectfully submitted,

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